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10/052,528	01/17/2002	Edward E. Elson	0229	3232

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EXAMINER

RODRIGUEZ, CRIS LOIREN

ART UNIT PAPER NUMBER

3763

DATE MAILED: 03/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,528

Applicant(s)

ELSON ET AL.

Examiner

Cris L. Rodriguez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 28-31, 33 and 40-44 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-12, 14-21, 23-27, 34-39, 53 and 55-60 is/are allowed.
- 6) ☒ Claim(s) 13, 32, 45-47, 51, 52 and 61 is/are rejected.
- 7) ☒ Claim(s) 22, 48-50 and 54 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Reissue Applications

1. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-27, 32, 34-39 and 45-61, drawn to a needle point guard safety cap assembly and a needle point shield, classified in class 604, subclass 192.
 - II. Claims 28-31, drawn to needle-protected hypodermic syringe, classified in class 604, subclass 197.
 - III. Claim 33, drawn to method of assembly, classified in class 29, subclass 428.
 - IV. Claims 40-44, drawn to method of protecting the needle tip of a hypodermic needle, classified in class 604, subclass 500.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the syringe combination does not require the particulars of the subcombination needle point guard safety assembly. The subcombination has separate utility such as needle guard.

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4. Inventions III and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as a process of protecting an IV needle by assembling a needle guard into it.

5. Inventions IV and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as in intravenous needle.

6. Inventions III and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as a process of protecting an IV needle by assembling a needle guard into it.

7. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

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product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as in an intravenous needle.

8. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different function and effect such as first the process of assembling a needle-protective hypodermic syringe, and subsequently the process of using and protecting the tip after being used.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

10. **Pursuant 37 CFR 1,176 a restriction between subject matter of the original patent claims and previously unclaimed subject matter is required. The subject matter of the original patent claims will be held to be constructively elected unless a disclaimer of all the patent claims is filed in the reissue application, which disclaimer cannot be withdrawn by applicant. SEE MPEP 1450.**

11. Newly submitted claims 28-31, 33, and 40-44 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: see the restriction above, and MPEP 1450.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28-31, 33, and 40-44 are withdrawn from

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consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

- ~~12.~~ The disclosure is objected to because of the following informalities: col. 7 line 33, reference numeral "13?" is incorrect. Appropriate correction is required.

Claim Objections

- ~~13.~~ Claim 54 is objected to because of the following informalities: "othr" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- ~~15.~~ Claims ~~32~~, ~~45-47~~, ~~51~~ and ~~61~~ are rejected under 35 U.S.C. 102(e) as being anticipated by Jenkins (US 5,700,249).

Jenkins discloses a needle-point protector having the elements as claimed. The protrusion 25 works as a ridge as claimed which also has a pivot support as seen in Figure 6.

- ~~16.~~ Claims ~~13~~ and ~~61~~ are rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan et al (US 5,250,031).

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Kaplan teaches a needle cover having the elements as claimed.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins in view of Kaplan et al.

Jenkins discloses the invention substantially as claimed. However, Jenkins fails to disclose a frame locking means to keep the frame in its extended position.

Kaplan teaches, figure 6, needle cover having a clamp 52 to retain the spring arms in an extended position. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include Kaplan's clamp into Jenkins's needle protector. Doing so would have improved and prevented retraction of the needle tip cover with a secondary locking.

Allowable Subject Matter

19. Claims 22, and 48-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

20. Claims 1-12, 14-21, 23-27, 34-39, 53, 55-60 are allowable over the prior art of record.

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21. Claim 54 is objected and would be allowable if amended to overcome set forth in this office action.

Conclusion


22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Haber et al, Di Cesare, Sweeney et al, Marks, Nestell, and Mercereau.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

March 10, 2003


Cris L. Rodriguez
Examiner
Art Unit 3763


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700